

REMARKS

The Present Invention

The present invention provides a complex comprising a virion having a surface and a lumen and comprising viral capsid proteins. The present invention further provides a method of inoculating a mammal, a method of immunizing a mammal, and a pharmaceutical composition comprising a complex and a physiologically-acceptable carrier.

The Pending Claims

Claims 1-6, 8-19, 21-32, 40, and 43-54 are currently pending. Claims 1-6, 8-18, 46, 47, and 52 are directed to the complex, claims 19, 21-25, 48, and 49 are directed to the method of inoculating a mammal, claims 26-32, 50, 51, and 53 are directed to the method of immunizing the mammal, and claims 40, 43-45, and 54 are directed to the pharmaceutical composition.

The Office Action

Claims 1-6, 8-17, 19, 21-24, 26-31, 40, 43, 44, 46, 48, 50, and 52-54 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent 5,846,782 (Wickham et al.) and Kikuchi et al., *Hum. Gene Ther.*, 10, 1375-1387 (1999). Claims 18, 25, 32, 45, 47, 49, and 51 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of the disclosures of the Wickham '782 patent and the Kikuchi reference in further view of Janeway et al., *Immunobiology*, 3rd ed., Garland Publishing, Inc., p. 727 (1997), or Ashkar et al., *Science*, 287, 861-864 (2000). Reconsideration of these rejections is hereby requested.

Discussion of Rejections Under 35 U.S.C. § 103(a)

The Office Action has maintained the rejections of the pending claims under Section 103 as allegedly encompassing obvious subject matter in view of the Wickham '782 patent and the Kikuchi reference, by themselves or in further view of the disclosure of the Janeway reference or the disclosure of the Ashkar reference. These rejections are respectfully traversed for the reasons set forth below.

To establish a *prima facie* case of obviousness under Section 103 based on a combination of references, (i) the references must disclose or suggest every element of the claimed invention, (ii) there must be a motivation to combine the references, and (iii) the combination of references must provide a reasonable expectation of success for making the claimed invention. M.P.E.P. § 2143.

According to the Office Action, the Wickham '782 patent discloses an adenoviral vector containing a modified fiber protein comprising a non-native ligand, which also encodes a passenger gene, the product of which can elicit a strong immune response that produces a therapeutic effect. The Office Action alleges that the Kikuchi reference discloses a recombinant adenovirus expressing the CD40 ligand (CD40L). The Office Action then concludes that one of ordinary skill in the art would have been motivated to express a CD40 ligand on the surface of the adenovirus disclosed in the Wickham '782 patent to induce antigen presenting cells to present antigens to the cellular immune system. The Office Action concedes that neither the Wickham '782 patent nor the Kikuchi reference discloses an adenovirus expressing a second antigen at its surface, as required by all of the pending claims, but alleges that one of ordinary skill in the art would nonetheless be motivated to express a second antigen on the adenoviral surface to induce a specific immune response.

An allegation that one of ordinary skill in the art would have been motivated to combine references, let alone do so in a way necessary to arrive at a claimed invention, must be based on objective evidence such as a teaching in the cited references. The level of skill in the art cannot be relied upon to provide a suggestion to combine prior art references. See, e.g., M.P.E.P. § 2143.01. As discussed above, the Office Action alleges that one of ordinary skill in the art would be motivated to combine the disclosures of the Wickham '782 patent and the Kikuchi reference and then express a second antigen on the adenoviral surface, as required by the pending claims, without pointing to any evidence, such as in the cited references, that supports this allegation. Therefore, not only do the cited references fail to disclose or suggest every element of the claimed invention, the Office Action does not provide any objective evidence as to why one of ordinary skill in the art would be motivated to combine and then modify the disclosures of the cited references and express a second antigen on the adenoviral surface.

The Janeway and Ashkar references do not cure the various deficiencies of the Wickham and Kikuchi references vis-à-vis the pending claims. In particular, the Janeway and Ashkar references do not disclose or suggest a complex comprising (a) a virion having a surface and a lumen, (b) a nucleic acid encoding at least one first non-native antigen, and (d) at least one second non-native antigen displayed on the virion surface.

Thus, Applicants submit that the Office Action has not met its burden in establishing a *prima facie* case of obviousness. Accordingly, the Section 103 rejection is improper and should be withdrawn.

In re Appln. of Roelvink et al.
Application No. 09/617,569

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



Heather R. Kissling, Reg. No. 45, 790
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: November 24, 2003